LOUISIANA OYSTERS
louisiana oyster task force

April 19, 1999

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Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
Docket No. 98P-0504 **Submitted to: Documents Management Branch (HFA-305)**

To Whom It May Concern:

Please find the enclosed documents as respectfully submitted by the Louisiana Oyster Task Force:

(1) **COMMENT ON ISSUES RAISED BY THE PETITION TO ESTABLISH A PERFORMANCE STANDARD FOR *Vibrio vulnificus* SUBMITTED BY THE CENTER FOR SCIENCE IN THE PUBLIC INTEREST**
2) **REQUEST FOR DENIAL OF CENTER FOR SCIENCE IN THE PUBLIC INTEREST PETITION**

The Louisiana Oyster Task Force is made up of oyster industry representatives in Louisiana and are responsible for regulation of and assistance to the shellfish community. The representatives are as follows:

Alfred R. Sunseri, Chairman
Represents: Louisiana Oyster Dealers and Growers Association
James Antoon
Louisiana Department of Health and Hospitals
Len Bahr
Governor's Office of Coastal Activities
Major Keith LaCase
Louisiana Department of Wildlife and Fisheries
Ronald Dugas
Louisiana Department of Wildlife and Fisheries
Bartel John Taliancich
Delta Commercial Fisherman's Association
Rachel Sweeney
Louisiana Department of Natural Resources
Mike Voisin
Louisiana Oyster Dealers and Growers Association
Mitch Jurisich
Plaquemines Oyster Association
Wilson Voisin, Jr.
Terrebonne Oyster Association
Shane Bagala
Southwest Pass Oyster Lease Holders
Dennis Pixton
United Commercial Fishermen's Association

Your kind consideration to these matters is greatly appreciated.

Sincerely,

Alfred R. Sunseri, Chairman

1600 Canal Street, Suite 210
New Orleans, LA 70112
1.800.222.4017

98P-0504

C85

Comment on Issues Raised

by the

Petition to Establish a Performance Standard for *Vibrio vulnificus*

submitted by the

Center for Science in the Public Interest

Submitted to: Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Docket No. 98P-0504

Submitted by the
Louisiana Oyster Task Force
April 19, 1999

Louisiana Oyster Task Force
1600 Canal Street, Suite 210
New Orleans, Louisiana 70112

1. Is the AmeriPure Company technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

The technology appears to be readily employable. However, the issue of employability of the process and the product is far more complex an issue than, "Can the industry employ the process." There is ample evidence from consumers, retailers, and wholesalers that if the only choice is a processed product, they will not use oysters. They want the raw, untreated oyster available. Employing the process and producing an oyster that the market will not use is not a reasonable alternative for the industry. The Louisiana Oyster Task Force (LOTF) believes the consumer should have a choice which includes the traditional raw oyster. The LOTF supports the development of innovative post harvest treatments for oysters but opposes the mandatory requirement of those processes for all oysters.

2. Other than the AmeriPure Company process, what technologies, both present and anticipated, could significantly reduce the number of *Vibrio vulnificus* in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of *Vibrio vulnificus* to non-detectable levels?

As of today, there is only one Post Harvest Treatment which may reduce *Vibrio vulnificus* levels in shellfish to non-detectable levels, the Ameripure process. Future treatments which are anticipated are: individual quick freezing with carbon dioxide; high pressure processing; and irradiation. The LOTF supports the development of Post Harvest Treatments for shellfish but also believes that every consumer should be allowed to make an educated decision when he or she chooses to eat any food, including raw oysters. Since *Vibrio vulnificus* is not ordinarily injurious to the general population, requiring that all certified shellfish dealers process oysters to reduce *Vibrio vulnificus* levels to non-detectable would be an overly restrictive and unnecessary regulation. The LOTF opposes any regulation that would require oysters to be post harvest treated.

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

All four technologies appear reliable for reducing *Vibrio vulnificus* levels. However, while all these processes result in lowered *Vibrio vulnificus* levels at the conclusion of the process, there are other concerns raised regarding the safety of the product. Each process requires special handling practices after treatment, for example, some mildly heat treated product must be maintained at or below 38° Fahrenheit. Ignoring handling and storage throughout the market chain while requiring application of these technologies at the producer level is neither practical nor reasonable. Mishandling at market and distribution levels to increase or resurrect health hazards while adding regulation and cost at the producer level fails to protect the consumer and is discriminatory regulation. Lower temperature handling requirements for some heat treated products makes mishandling more likely.

4. Would a performance standard have to be as low as "nondetectable?" Do data exist that would permit the setting of a performance standard above "nondetectable?" If so, at what level? Should the fact that *Vibrio vulnificus* is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

There is no established link between *Vibrio vulnificus* levels and illness or death. For this reason, no performance standard should be established.

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

The petition speaks to all species of molluscan shellfish, and there is potential implication of clams associated with some *Vibrio vulnificus* illnesses. We do not believe there should be a standard, however, if a standard is established, it should apply to all molluscan shellfish.

6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on costs be if a standard of "nondetectable" were put in place for all pathogens or for all raw shellfish?

Processing costs, labeling costs, and handling and storage costs would all increase. These costs would very likely have to be absorbed, at least in part, by the producing industry. Competing products in the market without the additional costs would provide incentive for the consumer to choose the less expensive alternative, resulting in lost market if the costs are simply passed along to the consumer. Many businesses in the Louisiana shellfish community could not afford the capitalization which would be required for post harvest treatment. They would be forced out of business or would have to sell their product to dealers who could process. This would change the structure of the market and reduce the value and business of these small operations. There would be a cultural loss, and perhaps a nutrition loss, that are not quantifiable. Since people first set foot on the shores of the world, they have consumed raw shellfish harvested from coastal waters. Establishing a performance standard of nondetectable would result in the loss of the raw market, particularly for Louisiana, and likely for other areas as scrutiny shifted to them with the closure of areas in Louisiana. The consumer would no longer have the choice of a live raw product. All processes result in changes in the form and texture of the product. We know that cooking results in changes which are frequently detrimental to the nutritional value of foods. This may also be the case in achieving a nondetectable performance standard. There would also be a loss of freedom of choice for the consumers. Allowing, even supporting and encouraging, Post-Harvest Treatment of oysters is far different from requiring Post-Harvest Treatment. Requiring treatment will take away the consumers' rights to choose what they want to eat.

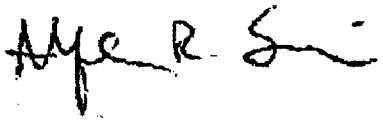
7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

The benefit of a performance standard would be that a very small group of vulnerable individuals, some small subset of the total at risk population, would be able to eat treated molluscan shellfish with reduced risk of *Vibrio vulnificus* caused illness or death. This small group numbers in the range of 15 to 20 per year out of a potential at risk population estimated by CSPI at 30 million. The group clearly represents some subset which for unknown reasons becomes particularly susceptible on a given occasion even though some members of the group may have eaten shellfish on other occasions with no health effects. The holder of patent rights to whatever process is mandated would also enjoy significant financial benefit as a result of the mandate.

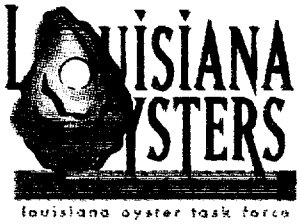
8. Another marine pathogen, *Vibrio parahaemolyticus*, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from *Vibrio parahaemolyticus* have occurred from oysters harvested outside the Gulf of Mexico region. Should a performance standard apply only to *Vibrio vulnificus* or should it apply to other Vibrio species that post-harvest treatment might be able to reduce to nondetectable levels?

There should not be a performance standard established for either *Vibrio vulnificus* or *Vibrio parahaemolyticus*. If the agency chooses to pursue this procedure for establishing a performance standard as a result of the petition submitted, it clearly should not include *Vibrio parahaemolyticus* since the petition does not raise that issue. The agency should refer this whole matter to the Interstate Shellfish Sanitation Conference for consideration through the established process for both *Vibrio vulnificus* and *Vibrio parahaemolyticus*.

Respectfully submitted,



Al Sunseri, Chairman



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Comments Submitted in regard to: Docket No. 98P-0504

Petition for Regulatory Action to Establish
A Standard for *Vibrio vulnificus* in Raw Molluscan
Shellfish of Undetectable Levels

Submitted by the
Louisiana Oyster Task Force
April 19, 1999

Louisiana Oyster Task Force
1600 Canal Street, Suite 210
New Orleans, Louisiana 70112

April 19, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

REQUEST FOR DENIAL OF

CENTER FOR SCIENCE IN THE PUBLIC INTEREST PETITION

IN TOTAL

These comments are submitted by the Louisiana Oyster Task Force in response to the Request for information and views from the general public published in the Federal Register, Volume 64, Number 13, page 3300, on Thursday, January 21, 1999. The Louisiana Oyster Task Force represents the shellfish community from the State of Louisiana as well as the bodies responsible for regulation of and assistance to the shellfish community. The Louisiana Oyster Task Force requests that the Food and Drug Administration deny the relief requested in the petition submitted by the Center for Science in the Public Interest requesting regulatory action to establish a regulation requiring nondeductible levels of *Vibrio vulnificus* in raw molluscan shellfish harvested from waters that have been linked to illnesses or deaths from these bacteria. The Louisiana Oyster Task Force requests that the petition be denied in total.

PREFACE

The Louisiana shellfish community is the number one producer of oysters in this country, having over one million acres of public oyster fisheries and more than 400,000 acres of farmed water bottoms under oyster cultivation. The Louisiana Oyster Task Force (LOTF) supports the Interstate Shellfish Sanitation Conference (ISSC) as the forum for addressing public health issues associated with molluscan shellfish. The U.S. Food and Drug Administration (FDA) has agreed in a Memorandum of Understanding (MOU) with the ISSC to, "Recognize the ISSC as the primary voluntary national organization of State shellfish regulatory officials that will provide guidance and counsel on matters for the sanitary control of shellfish." The ISSC has been diligently working on this issue for many years and has activities underway to continue dealing with the issue. The petitioner should be advised that the appropriate venue for submission of recommended actions or solutions to issues associated with molluscan shellfish is through the issue submission process of the ISSC. The ISSC process provides for deliberation of all issues submitted, with state regulatory authorities making the final decisions, and with a final review by FDA for consistency with federal laws, regulations, and policies, resulting in public health regulations which are rational, reasonable, science based, balanced, and cost effective. The deliberations emphasize protecting public health while producing the least possible regulatory impact on the shellfish community.

LOTF opposes the Center for Science in the Public Interest (CSPI) petition requiring a standard of nondeductible levels of *Vibrio vulnificus* (V.v.) in raw molluscan shellfish harvested from waters that have been linked to illnesses or deaths from these bacteria. Under section 402(a)(1) of the Federal Food Drug and Cosmetic Act (FFDCA), foods are not considered adulterated by a poisonous or deleterious substance if the substance is "naturally occurring" and "not ordinarily injurious." There is ample evidence cited in the CSPI petition which proves that V.v. is an organism which is naturally occurring in molluscan shellfish and is not ordinarily injurious. Therefore, adopting a standard of nondeductible is not reasonable and is unnecessary.

Louisiana was the first state implant the consumer advisory at the point of sale (February 1991) and the Louisiana shellfish community was among the first to place such information on product labeling. These efforts among others to educate at risk consumers have led to the state's success in reducing concerns related to V.v. while harvesting and selling near-record numbers of oysters. V.v. illnesses in Louisiana from oyster consumption have declined significantly since 1991. The LOTF considers the illness or death of any person as a result of shellfish consumption to be unfortunate and regrettable. However, in the case of V.v., all the information confirms that the problem lies with deficiencies in the vulnerable individuals which have made each individual particularly susceptible on a specific occasion. Shellfish containing V.v. are not contaminated or adulterated and do not cause illness in the vast majority of consumers.

Raw shellfish are clearly marketed as a "raw" product which any reasonable person would recognize as having some greater element of risk than the same product which has been cooked. The LOTF is concerned with consumption of raw molluscan shellfish by any person who is at-risk of illness or death because of that person's own underlying immune system problems. However, since many consumers can eat the same product without fear of illness or death, the LOTF does not believe that the shellfish community bears the responsibility for complying with a standard of nondeductible for all products to make them safe for all consumers, some of whom may have immune system problems. A consumer's personal health situation is the responsibility of that consumer and/or the person(s) legally responsible for that consumer. Requiring actions by the shellfish community to make raw shellfish safe for consumption by all persons, regardless of their health, or each individual's own knowledge of his/her individual health, is not reasonable.

RATIONALE FOR REQUESTING DENIAL OF PETITION

The FDA has agreed to use the ISSC process to develop regulations for sanitary control of molluscan shellfish. The FDA has repeatedly stated that it will look to the ISSC for guidance in regulating molluscan shellfish. Circumventing that process by taking unilateral action in adopting a regulation is not consistent with established FDA policy and procedure for molluscan shellfish.

The ISSC has been working on this issue for many years and has taken the appropriate, reasonable, science based actions to reduce V.v. illnesses and deaths. The ISSC has taken actions which are supported by public health professionals as the most effective, certainly the most cost-effective, for the funding which has been available. The educational efforts of the ISSC must have had an effect in reducing the number of seriously at-risk consumers eating raw shellfish or the numbers of illnesses and deaths reported would have increased as surveillance increased. ISSC decisions are made by the designated State Voting Delegates, representing the state shellfish control authorities. While the shellfish community provides input and participates throughout the process, even having equal voting privileges on the Task Forces which recommend actions to the final Voting Assembly, the final positions of the ISSC are established by the state shellfish agency Voting Delegates in open votes at that final Voting Assembly. This process was carefully established to prevent any possibility of compromising the positions of the ISSC. While the delegates are requested to consider economic impacts to the shellfish community and cost-effectiveness of proposed actions, they are also reminded at every Voting Assembly that their primary purpose is public health. The responsibility for ISSC positions, rests with the agency Voting Delegates.

The ISSC process includes a final review by the FDA of all proposed actions and positions. This review is stipulated in the MOU to determine consistency with FDA laws, regulations, and policies. The NSSP remains the property of the FDA. Since the FDA oversees the NSSP, it should look to its established processes for input and guidance on molluscan shellfish.

The evidence cited in the petition proves that V.v. is naturally occurring in raw shellfish. On page 10 the petition states, "One study found that in an 11-month period beginning in July 1996, there were only two weeks during which *Vibrio vulnificus* levels were nondeductible in oyster meat samples, the weeks of January 23 and February 4." On page 18, the petition references section 402(a)(4) of the FFDCA and cites this section to, "give FDA wide authority to require public health measures to reduce naturally-occurring pathogens during food processing.", claiming that this gives FDA authority to establish a performance standard in shellfish. The petition itself makes the case for V.v. being naturally occurring in raw shellfish.

The evidence cited in the petition also proves that raw shellfish containing V.v. are not ordinarily injurious. On page 5, the petition states that, "Since 1989. At least 89 people in the United States have died and at least another 88 have become seriously ill from eating molluscan shellfish contaminated with *Vibrio vulnificus*." On page 6, the petition makes the case that, "Between twelve and thirty million Americans, or as many as one in nine, have health conditions that put them at-risk of septicemia from *Vibrio vulnificus*, according to FDA estimates." Using the petition's own numbers and calculating the worst case percentage (20 illnesses and deaths combined per year divided by as few as 12 million at-risk), the relative risk is .00017%, less than two-millionths of one percent. Using the higher numbers for the at-risk population, the risk becomes even more negligible, and this is only for the at-risk group. Considering all raw shellfish consumers, raw shellfish containing V.v. are certainly "not ordinarily injurious." The numbers clearly indicate this is not a situation where the raw shellfish containing V.v. are ordinarily injurious. On page 9, the petition states, "The infectious dose for *Vibrio vulnificus* is unknown but at least one person has died and two have become ill from eating just one raw oyster each." This information emphasizes that the problem lies within the vulnerable individual not with the product. We know that many people in the at-risk group routinely consume many more shellfish at a single sitting during the warm weather months and presumably are exposed to many more V.v. organisms per sitting than the persons who ate only a single oyster. Yet these people exposed to higher levels of V.v. do not experience illness or death. For some unknown underlying reason within those three individuals, the persons likely exposed to fewer V.v. organisms did experience illness and death.

A Louisiana case resulted in the court ruling that oysters containing V.v. are not unreasonably dangerous to the ordinary consumer. This case was Simeon v. Doe, Louisiana Supreme Court, 618 SO.2d 848 (La. 1993). The Simeon court determined liability based on the determination of whether the oysters were "unreasonably dangerous." The court held that "unreasonably dangerous" has been defined as meaning "the article which injured the plaintiff was dangerous to an extent beyond that which would have been contemplated by an ordinary consumer." (Emphasis added). The Simeon court further held that the "unreasonably dangerous"

requirement came into our jurisprudence as a result of section 402(A) of the Restatement (Second) of Torts, which itself developed from common law statutes applying to persons supplying food and drink. Simeon, 618 SO.2d at 851. Comment I of section 402(A) makes it clear that a product is not "unreasonably dangerous" simply because it cannot be made "entirely safe for all consumption." Examples given in the comment show that while ordinary sugar is a "deadly poison" for diabetics and whiskey is "especially dangerous" to alcoholics, neither product is considered unreasonably dangerous. Applying the above doctrines, the Simeon court held that raw oysters containing V.v. are not unreasonably dangerous to the ordinary consumer. Specifically, the Louisiana Supreme Court provided the following: "The evidence is uncontroverted that *Vibrio vulnificus* bacteria in raw oysters poses little, if any, threat to a healthy person. The bacteria is only harmful to those persons with specific underlying disorders such as liver or kidney disease. Seen in this light, the 'defect' is really found in the person rather than the product, much in the same way that sugar is harmful only when used by someone with diabetes."

Raw shellfish, or shellfish "on-the-half-shell" are clearly marketed as a "raw " product, not subjected to the normal food safety process of cooking. There is no attempt to disguise the product or claim in any way that it is other than in its natural, raw state. Applying the test of a "reasonable person," it must be assumed that any reasonable person would recognize that consuming any product raw bears more risk of illness than when consuming the same product in cooked form. The NSSP was established to continue offering this product in the raw form with the risk of illness reduced as much as reasonably possible. The intent has never been, and is not now, to produce shellfish which are safe for any consumer to eat raw with no risk of illness regardless of the consumer's physical or health condition,

The petition makes a comparison of the V.v. in raw shellfish issue to the *Salmonella dublin* in milk issue. The *Salmonella dublin* issue resulted in requiring pasteurization of milk and the comparison is made to justify requiring the mild heat treatment process for reducing V.v. to nondeductible levels in shellfish. There are two distinct differences in the issues. First, *Salmonella dublin* is clearly ordinarily injurious and should be so regulated. V.v. as indicated previously, is not ordinarily injurious and should not be regulated. Second, pasteurization of milk, as required in the Pasteurized Milk Ordinance, adopted and enforced through the National Conference on Interstate Milk Shipments (NCIMS), is at levels of heat treatment and time periods to kill all pathogenic organisms in milk. The mild heat treatment process is at low temperature and has not been proven to eliminate all pathogens from shellfish, therefore, a case still cannot be made that the process renders the shellfish safe for all consumers, including those at-risk. Ironically, the pasteurization process used to make milk "safe" does not make it safe for all consumers. Some consumers are lactose intolerant and cannot drink even pasteurized milk without other health concerns even though the milk is free of pathogens. These lactose intolerant consumers must choose between medication for prevention of their individual problems, use of lactose free milk imitations, or forgoing the use of milk altogether.

CSPI comments and information submitted to the ISSC on issues have been skewed toward emotion regardless of potential effectiveness or economic impact on the shellfish community. When ISSC deliberations resulted in movement toward balance, reason, education, and science basis on these issues, CSPI has failed to work through the process, has resorted to one-sided news releases, and has generally derided the process because the ISSC did not "do it CSPI's way." LOTF is concerned about the use of the term pasteurization to refer to any mild heat treatment process for shellfish. The general usage of the term associated with products on the market (such as pasteurized milk) results in consumers believing that the product has been treated to eliminate all pathogens. LOTF believes that the use of this term may confuse consumers into thinking mild heat treated oysters are entirely safe. LOTF also questions the feasibility of maintaining mild heat treated product at or below 38° F throughout the market chain.

The petition raises the issue of whether the Seafood HACCP Regulation can be effective in controlling V.v. in raw oysters. Since the problem of illnesses and deaths is associated with deficiencies in the vulnerable individuals and not with defective products, HACCP would not likely result in decreases in the numbers of illnesses and deaths. As long as at-risk consumers ignore their health conditions, abandon the safety process of cooking their shellfish, and continue to eat raw shellfish, they will increase their individual risk beyond that provided by the NSSP, or even by HACCP, and V.v. illnesses and deaths will occur. For this reason, LOTF

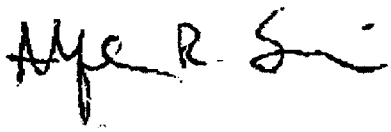
continues to support efforts to educate these at-risk consumers to eat their shellfish cooked, and even supports offering them alternative products such as post harvest treated products. However, LOTF cannot support requiring all product to meet a standard of nondeductible when it is clearly not reasonable or necessary for most consumers. Consumers should have a choice when eating oysters raw, on-the-half-shell. If an at-risk consumer chooses to eat raw oysters, then the product and the producer should not be blamed if illness or death occurs, any more than sugar or sugar producers are blamed when diabetics misuse sugar.

CONCLUSION

LOTF encourages FDA and CSPI to work through the ISSC process in cooperation with others who are making efforts to resolve the V.v. issue in raw molluscan shellfish.

LOTF requests the FDA to reject the petition and not adopt a performance standard.

Respectfully submitted,



Al Sunseri, Chairman

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16 ☐ FEDEX LETTER *	56 ☑ FEDEX LETTER *
12 ☐ FEDEX PAK *	52 ☐ FEDEX PAK *
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